# 510(K) SUMMARY

DEC 1 3 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is:	The assigned 510(k) number is:	
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#### 1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5635 Fax: +86 755 2658 2680

#### **Contact Person:**

Bai Yanhong Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

**<u>Date Prepared:</u>** September 7, 2012

2. <u>Device Name</u>: DC-N3/DC-N3S Diagnostic Ultrasound System

#### Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

# 3. Device Description:

DC-N3/DC-N3S is a mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B, M, PW, CW, Color, Power, HPRF, TVI, TEI,TVD, Free Xros M/ Free Xros CM, Smart 3D, 4D, iScape, or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased

array with a frequency range of approximately 2.5 MHz to 10.0 MHz.

#### 4. Intended Use:

DC-N3/DC-N3S Diagnostic Ultrasound System is applicable for adult, pregnant woman, pediatric and neonate. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes.), cephalic(neonatal and adult), trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(Adult and Pediatric), Peripheral Vascular and urology exams.

#### 5. Comparison with Predicate Devices:

DC-N3/DC-N3S Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

1 <u>41</u>	ratelit to these p	redicate devices.					
	Predicate Device	Manufacturer	Model	510(k) Control Number			
	1	Mindray	DC-7	K103583			
	2	Mindray	DC-T6	K120699			
	3	Mindray	DC-8	K113647			
	4	Mindray	Z6	K122010			

They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

### 6. Non-clinical Tests:

DC-N3/DC-N3S Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, UD 3, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, UL 60601-1, ISO14971 and ISO 10993-1.

#### **Conclusion:**

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-N3/DC-N3S Diagnostic Ultrasound System is

substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

December 13, 2012

Shenzhen Mindray Bio-Medical Electronics., Ltd. . % Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K123503

Trade/Device Name: The DC-N3/DC-N3S Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: October 31, 2012 Received: November 13, 2012

#### Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the The DC-N3/DC-N3S Diagnostic Ultrasound System as described in your premarket notification:

#### Transducer Model Number

3C5A	<u>L14-6</u>
6C2	<u>2P2</u>
V10-4	<u>D6-2</u>
V10-4B	D6-2A
7L4A	<u>6CV1</u>
T 12 4	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Janine M∆Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

# **Indications for Use**

510(k) Number (if known):

•
Device Name: The DC-N3/ DC-N3S Diagnostic Ultrasound System
Indications for Use:
The DC-N3/ DC-N3S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast thyroid, testes), cephalic (neonatal and adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional and superficial), cardiac (adult and pediatric), peripheral vascular and urology exams
Prescription Use X AND/OR Over – The – Counter Use (21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostic and Radiological Health (OIR)

Division of Badiological Health

Office of In Vitro Diagnostics and Radiological Health

Diag	gnostic	e Ultr	asound	l Indic	ations	for Use I	Form	
System .	×			Transdu				
Model:		D	C-N3		_			
510(k) Number(s)					-			
	Γ			<del></del>	Mode of (	Operation		
Clinical Application				· -	Color	Amplitud	Combined	
C02. 1 pp.100	В	М	PWD	CWD	Doppler		(specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2, 3, 4,6,7
Abdominal	N_	N	N	N	N	N	Ň	Note1,2, 3, 4,5,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)	<u> </u>		<u> </u>	ļ				
Laparoscopic								
Pediatric	N	N	N	N	N	N	. N	Note 1, 2, 4,5,6,7
Small organ(specify)**	N	N	N_		N	N	N	Note1, 2, 4,6,7
Neonatal Cephalic	N	N	N_	[ N	N	N	N	Note1, 2, 4,5,6,7
Adult Cephalic	N	N	N	N	N	N	N	Note1, 2, 4,5,6,7
Trans-rectal	N	N	N		N·	N	N	Note 1,2,4,6,7
Trans-vaginal	N	N	N		N	N	N	Note 1,2,4,6,7
Trans-urethral								
Trans-esoph.(non-Card.)				-				
Musculo-skeletal	N	N	N		N	N	N	Note 1,2,4,6,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2,4,6,7
Intravascular				,				
Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,5,6,7
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,5,6,7
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)			Ι					
Intra-Cardiac								
Peripheral Vascular	N	N	N		N	N	N	Note 1,2,4,6,7
Other (specify)***	N	N	N		N	N	·N	Note 1,2,4,6,7
N=new indication; P=previou	siy clear	ed by F	DA; E=a	ded und	er Append	lix E		
Additional comments:Combir							Color+ B, Po	ower + PW +B.
*Intraoperative inc	ludes at	domina	l, thoraci	c, and va	scular etc.			
**Small organ-bre	ast, thyr	oid, test	es, etc.		_			
. ***Other use inclu								
Note 1: Tissue Ha	monic I	maging	The feat	ure does	not use co	ntrast agen	ts.	
Note 2: Smart3D								
Note 3:4D(Real-ti	me 3D)			_				
Note 4: iScape								
Note5: TDI								
Note6: Color M						<del></del>	-	
Note7: Biopsy Gu							00.00.00	
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

Division of Radiological Health

Office of in Vitro Diagnostics and Radiological Health

510M K123503

System				Transduc	сег	<u>×</u>		•		
Model:		. 3	C5A		_					
510(k) Number(s)			_		_					
	Mode of Operation									
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)		
Ophthalmic										
Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7		
Abdominal	N	N	N		N	N _	N	Note 1, 2, 4,6,7		
Intraoperative (specify)*										
Intraoperative (Neuro)										
Laparoscopic										
Pediatric	N	N	N		N	N_	N	Note 1, 2, 4,6,7		
Small organ(specify)**					]					
Neonatal Cephalic										
Adult Cephalic										
Trans-rectal										
Trans-vaginal ,		_								
Trans-urethral										
Trans-esoph (non-Card.)			1							
Musculo-skeletal	N	N	N	l	N	N	N	Note 1, 2, 4,6,7		
Musculo-skeletal Superficial			.T.,	<u> </u>						
Intravascular	-									
Cardiac Adult										
Cardiac Pediatric					-					
Intravascular (Cardiac)				[	Ţ		<u> </u>			
Trans-esoph.(Cardiac)						<u> </u>	ļ			
Intra-Cardiac			Ī	<u> </u>		<u> </u>				
Peripheral Vascular	N	N	N		N	N	N	Note 1, 2, 4,6,7		
Other (specify)***						<u> </u>	<u> </u>			
N=new indication; P=previou	sly clear	ed by F	DA; E=a	dded und	er Append	ix E				
Additional comments:Combin							Color+ B, Po	ower + PW +B.		
*Intraoperative inc										
**Small organ-bre	ast, thyr	oid, tes	tes, etc.							
***Other use inclu	ides Uro	logy.								
Note 1: Tissue Ha	monic I	maging	. The feat	ture does	not use co	ntrast agen	ts.			
Note 2: Smart3D								<u> </u>		
Note 3:4D(Real-ti	me 3D)									
Note 4: iScape										
Note5: TDI							·			
Note6: Color M								<del> </del>		
Note7: Biopsy Gu										
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Division of Radiological Health

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System		_	C	Transduc	:61	<u>×</u>	•	
Model:			C2		-			
510(k) Number(s)	<u></u>	<del></del> -			•			
	. Mode of Operation							
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud	1	Other (specify)
Ophthalmic		_						
Fetal								
Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								<u> </u>
Laparoscopic					_			
Pediatric	N	N	N		N_	N	N	Note 1, 2, 4,6,7
Small organ(specify)**				_	<u> </u>			
Neonatal Cephalic	N	N	N	[	N.	N	N	· Note 1, 2, 4,6,7
Adult Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6,7
Trans-rectal					ļ	<u></u>		
Trans-vaginal					<u> </u>			
Trans-urethral				<u> </u>	<u> </u>	<u></u>	ļ	
Trans-esoph.(non-Card.)			<u> </u>	l				_
Musculo-skeletal	N	N	N	İ	N	N	N	Note 1, 2, 4,6,7
Musculo-skeletal Superficial	N	N	N	Ĭ	N	N	N	Note 1, 2, 4,6,7
Intravascular				<u> </u>				
Cardiac Adult	N	N	N		N	· N	N	Note 1, 2, 4,6,7
Cardiac Pediatric	N	N	N		N	N	N_	Note 1, 2, 4,6,7
Intravascular (Cardiac)			<u> </u>	<u> </u>	<u> </u>		ļ	
Trans-esoph.(Cardiac)			<u> </u>	<u></u>			<u> </u>	ļ. <u> </u>
Intra-Cardiac						<u> </u>		
Peripheral Vascular	N	N	N	Τ	N	N	N	Note 1, 2, 4,6,7
Other (specify)***					<u> </u>	<u> </u>	<u> </u>	<u> </u>
N=new indication; P=previou	sly clear	red by F	DA; E=a	dded und	er Appen	dix E		
Additional comments:Combin	ned mod	es: B+N	1, PW+B	, Color +	B, Power	+ B, PW +	Color+B, Po	ower + PW +B.
*Intraoperative inc	ludes at	odomina	ıl, thorac	ic, and va	scular etc			
**Small organ-bre	ast, thyr	oid, tes	tes, etc.					
***Other use inclu							<u> </u>	
Note 1: Tissue Ha	rmonic I	lmaging	. The fea	ture does	not use co	ontrast agen	ts.	
Note 2: Smart3D	<u>.                                    </u>							
Note 3:4D(Real-ti	me 3D)							
Note 4: iScape								
Note5: TDI							<del> </del>	
Note6: Color M		_						
Note7: Biopsy Gu	idance					OWLED D.	CE IE NEE!	DED)
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Concurrence of CDRH, Office of Device Evaluation(QDE)

Prescription USE (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

System				Transdu	cer	×				
Model:	V10-4						•			
510(k) Number(s)	-				-					
., .,					<u> </u>					
	Mode of Operation									
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)		
Ophthalmic			<u> </u>							
Fetal	N	N	N	i	N	N	N	Note 1, 2, 4,6,7		
Abdominal										
Intraoperative (specify)*					<u> </u>					
Intraoperative (Neuro)			<u> </u>							
Laparoscopic					ļ					
Pediatric		•								
Small organ(specify)**					<u> </u>					
Neonatal Cephalic			<u> </u>							
Adult Cephalic			<u> </u>				· .	.,		
Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7		
Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7		
Trans-urethral										
Trans-esoph.(non-Card.)				<u> </u>						
Musculo-skeletal										
Musculo-skeletal Superficial				<u></u>						
Intravascular				<u> </u>						
Cardiac Adult										
Cardiac Pediatric										
Intravascular (Cardiac)								-		
Trans-esoph.(Cardiac)			<u> </u>							
Intra-Cardiac	İ			<u> </u>						
Peripheral Vascular			<u>l</u>	<u> </u>		<u></u>				
Other (specify)***	N	N	N		N	N	N	Note 1, 2, 4,6,7		
N=new indication; P=previou	sly clear	ed by F	DA; E=a	ided unde	er Append	lix E				
Additional comments:Combin	ed mode	es: B+M	I, PW+B,	Color +	B, Power	+ B, PW +0	Color+ B, Po	wer + PW +B.		
*Intraoperative inc	ludes ab	domina	l, thoraci	c, and vas	scular etc.					
**Small organ-bre	ast, thyre	oid, test	es, etc.							
***Other use inclu	des Uro	logy.								
Note 1: Tissue Har	monic I	maging.	The feat	ure does	not use co	ntrast agent	S			
Note 2: Smart3D										
Note 3:4D(Real-tin	me 3D)									
Note 4: iScape							<del> </del>			
Note5: TDI								· · ·		
Note6: Color M										
Note7: Biopsy Gui										
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Prescription USE (Per 21	CFR 8	0 i <b>L1</b> 65	$\mathcal{L}$		12					

Office of in Vitro Diagnostics and Radiological Health

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System				Transdu	cer	×	-	
Model:	V10-4B							
510(k) Number(s)			·		_			
					Mode of	Operation		
Clinical Application	В	М ,	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)
Ophthalmic				l				
Fetal	N	N	N		N	N	N	Pote 1, 2, 4,6,7
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								-
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7
Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7
Trans-urethral			1.					
Trans-esoph.(non-Card.)		-	<u> </u>		ĺ			·
Musculo-skeletal				1				
Musculo-skeletal Superficial			1					
Intravascular								
Cardiac Adult				٠.				
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)				l		1		
Intra-Cardiac								
Peripheral Vascular			T					
Other (specify)***	N	N	N		N	N	N	Note 1, 2, 4,6,7
N=new indication; P=previou	sly clear	ed by Fl	DA; E=ac	ded unde	er Append	ix E		
Additional comments:Combin	ed mode	es: B+M	, PW+B,	Color +	B, Power	+ B, PW +0	Color+ B, Po	wer + PW +B.
*Intraoperative inc	ludes ab	domina	l, thoraci	c, and vas	cular etc.			_
**Small organ-bre	ast, thyr	oid, test	es, etc.					
***Other use inclu	ides Uro	logy.						
Note 1: Tissue Har	monic I	maging.	The feat	ure does i	not use co	ntrast agent	<b>S</b> .	
Note 2: Smart3D								
Note 3:4D(Real-tin	me 3D)							
Note 4: iScape								<u> </u>
Note5: TDI								
Note6: Color M								
Note7: Biopsy Gui								
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Office of in Vitro Diagnostics and Radiological Health

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System				Transduc	cer	×		
Model:	7L4A				•			
510(k) Number(s)			<del></del>		•			,
					•			
	Mode of Operation							
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
Small organ(specify)**	N	N	N		N	N	·N	Note 1,2, 4,6,7
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,6,7
Adult Cephalic								
Trans-rectal	,							
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)						T	·	
Musculo-skeletal	N	N	N		N	N	N	Note 1,2, 4,6,7
Musculo-skeletal Superficial	N	N	N	1	N	N	N	Note 1,2, 4,6,7
Intravascular			1				1	
Cardiac Adult						Ì		-
Cardiac Pediatric				ĺ	1 "			
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N ·	N		N	N	N	Note 1,2, 4,6,7
Other (specify)***								
N=new indication; P=previous	sly clear	ed by F	DA; E=a	dded unde	er Append	lix E	•	
Additional comments:Combin	ed mod	es: B+M	I, PW+B,	Color +	B, Power	+ B, PW +0	Color+ B, Po	wer + PW +B.
*Intraoperative inc	ludes at	domina	l, thoraci	c, and vas	cular etc.			
**Small organ-bre	ast, thyr	oid, test	es, etc.					
***Other use inclu								
Note 1: Tissue Har	monic I	maging.	The feat	ure does	not use co	ntrast agent	s.	
Note 2: Smart3D								
Note 3:4D(Real-tii	ne 3D)							
Note 4: iScape								
Note5: TDI								
Note6: Color M								
Note7: Biopsy Gui					<u> </u>			
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Prescription USE (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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System				i ransdu	cer	<u>×</u>	-				
Model:		L	12-4		-						
510(k) Number(s)					-						
				<u> </u>							
	Mode of Operation										
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)			
Ophthalmic											
Fetal											
Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7			
Intraoperative (specify)*											
Intraoperative (Neuro)					Ĭ						
Laparoscopic											
Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7			
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,6,7			
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,6,7			
Adult Cephalic					ì						
Trans-rectal											
Trans-vaginal					I						
Trans-urethral											
Trans-esoph.(non-Card.)			Ī								
Musculo-skeletal	N	N	N		N	N	N	Note 1,2, 4,6,7			
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,6,7			
Intravascular											
Cardiac Adult											
Cardiac Pediatric											
Intravascular (Cardiac)				]			<u>                                     </u>				
Trans-esoph.(Cardiac)		[ <u> </u>		<u> </u>							
Intra-Cardiac		·		<u> </u>		<u> </u>					
Peripheral Vascular	N	Ŋ	N		N	N	N	Note 1,2, 4,6,7			
Other (specify)***			<u> </u>	<u> </u>		l	<u> </u>				
N=new indication; P=previou											
Additional comments:Combin	ned mod	es: B+N	1, PW+B	Color +	B, Power	+ B, PW +0	Color+ B, Po	wer + PW +B.			
*Intraoperative inc	ludes at	domina	l, thoraci	c, and va	scular etc.						
**Small organ-bre	ast, thyr	oid, test	es, etc.								
***Other use inclu	ıdes Uro	logy.									
Note 1: Tissue Ha	rmonic I	maging.	The feat	ure does	not use co	ntrast agen	ts.				
Note 2: Smart3D											
Note 3:4D(Real-ti	me 3D)			•		-					
Note 4: iScape											
Note5: TDI							·				
Note6: Color M							-				
Note7: Biopsy Gu											
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Concurrence of CDRH	i, Offic	e of D	evice F	valuat	ion(OD	<u> </u>					
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Prescription USE (Per 21	CFR 8	301.109	) (	レヘイ	111-1	1 1/1d/	1,				

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510M K123503

System	เมอรมเ	COILL	asounc	Transdu		×		•
Model:		L	14-6				•	
510(k) Number(s)					-			
STO(K) Number(s)	<u> </u>				<u> </u>			
	Mode of Operation							
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal				<u> </u>				
Abdominal	N	N_	N		N	N	N	Note 1,2, 4,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)		<u> </u>	<u> </u>	<u> </u>	<u> </u>			<u> </u>
Laparoscopic			<u>l</u>					
Pediatric	N	N	N	_	N .	N	N	Note 1,2, 4,6,7
Small organ(specify)**	N	N	N		N	N_	N	Note 1,2, 4,6,7
Neonatal Cephalic	N	. N	N		N	N	N	Note 1,2, 4,6,7
Adult Cephalic				<u> </u>				
Trans-rectal		Ī.						
Trans-vaginal		L.		<u> </u>	<u> </u>	ļ		
Trans-urethral			<u> </u>	<u> </u>		<u> </u>		
Trans-esoph.(non-Card.)			ļ	<u> </u>				
Musculo-skeletal	N	N	N		N	N	N	Note 1,2, 4,6,7
Musculo-skeletal Superficial	N	N	N	<u> </u>	N	N	N	Note 1,2, 4,6,7
Intravascular						<u> </u>		
Cardiac Adult							<u> </u>	
Cardiac Pediatric			<u>L</u>	<u> </u>			· ·	
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)				<u> </u>		<u> </u>	ļ.·	
Intra-Cardiac	<u> </u>	<u> </u>					ļ	
Peripheral Vascular	N	N	N		N	N_	N	Note 1,2, 4,6,7
Other (specify)***	<u> </u>			<u> </u>	<u> </u>	<u> </u>		<u></u>
N=new indication; P=previou	sly clea	red by F	DA; E=a	dded und	ler Appen	dix E		
Additional comments: Combin	ned mod	les: B+N	1, PW+B	, Color +	B, Power	+ B, PW +	Color+ B, Po	ower + PW +B.
*Intraoperative inc				ic, and va	scular etc			
**Small organ-bre	ast, thy	roid, tes	tes, etc.				<del></del>	
***Other use inclu							<del></del>	
Note 1: Tissue Ha	rmonic	Imaging	. The fea	ture does	not use co	ontrast ager	its.	
Note 2: Smart3D								
Note 3:4D(Real-ti	me 3D)						<del></del> .	
Note 4: iScape							<del></del>	
Note5: TDI								
Note6: Color M							<del> </del>	
Note7: Biopsy Gu		.,	LDE C	ANTENIO P	CON AND	OTHED DA	GE IE MEET	DEDI
(PLEASE DO NOT WRITE							OE II NEE	
Concurrence of CDRH	<u>ı, Offi</u>	ce of I	Jevice l	Lvaluat	tion(OD	E)		

Prescription USE (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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System				Transdu	cer	<u>×</u>				
Model:	2P2									
510(k) Number(s)					_					
		Mode of Operation								
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)		
Ophthalmic										
Fetal										
Abdominal	N	N	N _	N	N	N.	N	Note 1, 2,4,5,6,7		
Intraoperative (specify)*										
Intraoperative (Neuro)										
Laparoscopic				ĺ						
Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7		
Small organ(specify)**			1							
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,6,7		
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7		
Trans-rectal				ļ						
Trans-vaginal	1				Ī					
Trans-urethral	T									
Trans-esoph.(non-Card.)	T			<u> </u>						
Musculo-skeletal			<u> </u>	<u> </u>		ļ				
Musculo-skeletal Superficial	T			ļ			<u> </u>			
Intravascular				<u> </u>	_					
Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7		
Cardiac Pediatric	N	N	N_	N	N	N	N	Note 1, 2,4,5,6,7		
Intravascular (Cardiac)	T				<u> </u>	<u> </u>				
Trans-esoph (Cardiac)	T					<u> </u>	<u> </u>			
Intra-Cardiac				<u> </u>						
Peripheral Vascular	T					<u> </u>				
Other (specify)***	1		1			<u> </u>	<u> </u>	<u></u>		
N=new indication; P=previou										
Additional comments:Combi							Color+ B, P	ower + PW +B.		
*Intraoperative in	cludes at	odomina	ıl, thoraci	c, and va	scular etc.					
**Small organ-br	east, thyr	oid, tes	tes, etc.					<u></u>		
***Other use incl										
Note 1: Tissue Ha	ırmonic I	maging	. The feat	ure does	not use co	ntrast agen	ts.			
Note 2: Smart3D										
Note 3:4D(Real-t	ime 3D)					<u> </u>				
Note 4: iScape										
Note5: TDI							_	<del></del>		
Note6: Color M	-,					<del></del>		<del></del>		
Note7: Biopsy Gu			LINE CO	APPEND OF	CONTANT	THE DA	CE IE MEC	DEDI		
(PLEASE DO NOT WRITE							GE IF NEEL	<u> </u>		
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Prescription USE (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510M K123503

System			26.2	Hansuu	ÇEI	<u> </u>	•			
Model:			06-2		-					
510(k) Number(s)					-					
		:			Mada of	Ownerstion				
Clinical Application	Mode of Operation  Color   Amplitud   Combined   Combin									
	В	М	PWD	CWD	Doppler	Amplitud e Doppler		Other (specify)		
Ophthalmic										
Fetal	N	N	N		N	N	N_	Note1,2, 3, 4,6		
Abdominal	N	N	N		N	N	N	Note 1,2, 3, 4,6		
Intraoperative (specify)*			1		<u>.                                    </u>					
Intraoperative (Neuro)										
Laparoscopic			1							
Pediatric										
Small organ(specify)**			<u> </u>		<u></u>					
Neonatal Cephalic										
Adult Cephalic							ļ. <u>.                                   </u>			
Trans-rectal					ļ					
Trans-vaginal										
Trans-urethral			<u>.                                    </u>				<b> </b>			
Trans-esoph.(non-Card.)			ļ		ļ					
Musculo-skeletal			<u> </u>			ļ				
Musculo-skeletal Superficial			ļ	<u> </u>						
Intravascular										
Cardiac Adult			ļ			1				
Cardiae Pediatric			<u> </u>	<u> </u>						
Intravascular (Cardiac)				<u> </u>	<u> </u>	<u> </u>		<u> </u>		
Trans-esoph.(Cardiac)						<u> </u>	ļ			
Intra-Cardiac					ļ					
Peripheral Vascular					ļ	ļ				
Other (specify)***						<u> </u>				
N-new indication; P-previous	ly clear	ed by Fl	DA; E=ac	ided unde	r Append	ix E				
Additional comments: Combin	ed mode	s: B+M	I, PW+B,	Color +	B, Power	+ B, PW +0	Color+ B, Po	wer + PW +B.		
*Intraoperative inc	ludes ab	domina	I, thoraci	, and vas	cular etc.		<u> </u>			
**Small organ-bre	ast, thyro	oid, test	es, etc.		·			·		
***Other use inclu										
Note 1: Tissue Har	monic II	maging.	The feat	ure does r	not use co	ntrast agent	s			
Note 2: Smart3D										
Note 3:4D(Real-tir	ne 3D)									
Note 4: iScape										
Note5: TDI										
Note6; Color M	<del></del>									
Note7: Biopsy Gui										
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Concurrence of CDRH	, Offic	e of D	evice E	valuati	on(ODI	S)				
Prescription USE (Per 21	CFR 8	01.109	)		an	~}	har	· ·		

Office of In Vitro Diagnostics and Radiological Health

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System				Transdu	сег	×		
Model:	D6-2A							
510(k) Number(s)					-			
, <del></del>								
					Mode of (	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2, 3, 4,6
Abdominal	N	N	N		N	N	N	Note1,2, 3, 4,6
Intraoperative (specify)*								
Intraoperative (Neuro)	٠				_			
Laparoscopic .								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal	. :							
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal							ĺ	
Musculo-skeletal Superficial								<del></del>
Intravascular				_				
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular						_		
Other (specify)***		_						
N=new indication; P=previous	ly cleare	d by FI	A; E=ad	ded under	Appendi	хE	<u> </u>	
Additional comments:Combin							olor+ B, Pov	ver + PW +B.
*Intraoperative inc								
**Small organ-brea	ast, thyro	id, teste	s, etc.	"				
***Other use inclu	des Urol	ogy.						• •
Note 1: Tissue Har	monic Ir	naging.	The featu	re does n	ot use con	trast agents	i.	
Note 2: Smart3D								
Note 3:4D(Real-tir	ne 3D)							
Note 4: iScape					=.			
Note5: TDI								
Note6: Color M								
Note7: Biopsy Guid				•				
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Concurrence of CDRH.	Office	of De	vice Ev	valuatio	n(ODE	) 1		
Prescription USE (Per 21	CFR 80	01.109)	(	(Divisio	Au m Sign O	n fi	har	
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System				Transduc	er	×			
Model:		. 60	CVI			•			
510(k) Number(s)					-				
	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Combined (specify)	Other (specify)	
Ophthalmic						_			
Fetal	N	N	N	<u> </u>	N	N	N	Note1,2, 4,6,7	
Abdominal			ļ						
Intraoperative (specify)*									
Intraoperative (Neuro)			<u> </u>	ļ <u></u>					
Laparoscopic			<u> </u>						
Pediatric				ļ					
Small organ(specify)**				<u> </u>					
Neonatal Cephalic			<u> </u>	<u> </u>		-			
Adult Cephalic		<u> </u>						<u> </u>	
Trans-rectal	N	N	N		N	N	N	Note1,2, 4,6,7	
Trans-vaginal	N	N	N		N	N	N	Note1,2, 4,6,7	
Trans-urethral			<u> </u>						
Trans-esoph.(non-Card.)				<u> </u>					
Musculo-skeletal									
Musculo-skeletal Superficial									
Intravascular			<u> </u>						
Cardiac Adult			<u> </u>						
Cardiac Pediatric	L								
Intravascular (Cardiac)			<u> </u>					=	
Trans-esoph.(Cardiac)			<u> </u>					<del></del> -	
Intra-Cardiac									
Peripheral Vascular				,					
Other (specify)***	N	. N	N		N	N_	N	Note1,2, 4,6,7	
N=new indication; P=previous	sly clear	ed by FI	OA; E≕ac	lded unde	r Append	ix E	•		
Additional comments:Combin	ed mode	es: B+M	, PW+B,	Color + I	3, Power	+ B, PW +0	Color+ B, Po	wer + PW +B.	
*Intraoperative inc	ludes ab	domina	, thoraci	c, and vas	cular etc.				
**Small organ-bre	ast, thyr	oid, test	es, etc.						
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note 2: Smart3D									
Note 3:4D(Real-time 3D)									
Note 4: iScape									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Gui		TT IIC I	D.IE. 00:	TEN II IE	011 4 110	THE DAG	OF IE MEET	TD)	
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Concurrence of CDRH	, Offic	e of D	evice E	valuatio	on(Onf	<del>(</del> ) _	<del>-  -  -  </del> -		
Prescription USE (Per 21	CFR 8	01.109	) (-	1	X	am	Sh	ar-	
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